REMARKS

The Examiner rejected claims 21-40, while acknowledging that claims 21-28 appear free of the prior art. Claims 21-40 have been canceled without prejudice, and claims 41-48 have been added herein as rewritten versions of claims 21-28. Thus, claims 41-48 are pending.

Applicants' specification fully supports new claims 41-48. For example, the sections extending form page 4, line 10 to page 5, line 11 and from page 9, line 7 to page 9, line 19 of Applicants' specification disclose increasing polypeptide expression after a delay. Page 4, lines 19-20 disclose that the mammal already exhibits an immune response to the polypeptide. Page 4, lines 12-15 disclose that the cell contains nucleic acid having regulatable promoter operably linked to the sequence encoding the polypeptide. The section extending from page 4, line 25 to page 5, line 6 discloses that expression of the polypeptide by the cell is substantially inhibited *in vitro*. This section as well as page 4, lines 12-15 disclose altering the concentration of an inducing agent to cause an increase in expression of the polypeptide at a time point after the introducing step. Page 6, lines 20-32 discloses altering the concentration of an inducing agent by increasing or decreasing the amount. Thus, no new matter has been added.

In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 41-48.

Examiner Interview

Applicant's agent thanks Examiner Wilson for the courtesy of the telephonic interview on March 18, 2003. The substance of this telephonic interview involved the 35 U.S.C. § 112 rejections of the Office Action mailed December 19, 2003 as they relate to claim 21-28. During that telephonic interview, the Examiner generously provided several possible claim language suggestions. For convenience, claims 21-28 have been cancelled herein and rewritten as claims 41-48. In addition, claims 29-40 have been cancelled without prejudice.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 21-40 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner questioned the support of several phrases in claim 21. In addition, the Examiner stated that support for claims 26 and 27 was not provided and cannot be found. The Examiner also stated that claims 29, 32, 35, and 38 constitute new matter.

Applicants respectfully disagree. Applicants' specification fully supports claims 21-40. To further prosecution, however, claims 21-40 have been cancelled without prejudice. Thus, this rejection is moot.

Claims 21-28 have been rewritten for convenience as claims 41-48. Applicants' specification fully supports claims 41-48 as outlined above.

The Examiner also rejected claims 21-40 under 35 U.S.C. § 112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims for the reasons of record. Specifically, the Examiner stated that the "specification does not provide adequate guidance to obtain a therapeutic effect by increasing expression of the protein *in vivo*."

Applicants respectfully disagree. Applicants' specification as filed fully enables claims 21-40. As noted above, claims 21-40 have been cancelled without prejudice, and claims 21-28 have been rewritten as claims 41-48.

New claims 41-48 recite methods for delaying maximum polypeptide expression. The presently claimed methods require obtaining the recited mammal and cell, introducing the cell into the mammal, and increasing or decreasing the concentration of an inducing agent to which the cell is exposed thereby causing an increase in expression of the polypeptide. At no point do the present claims recite a step of obtaining a therapeutic effect. Again, the claims recite causing an increase in expression of the polypeptide.

Applicants' specification as filed fully enables the presently claimed methods. In fact, after reading Applicants' specification, a person having ordinary skill in the art at the time Applicants filed would have been able to carry out the presently claimed methods without undue experimentation whether or not a therapeutic effect is obtained. For example, a person having ordinary skill in the art would have been able to use routine procedures to obtain (1) a mammal

that exhibits an immune response against a polypeptide and (2) cells having a vector containing a regulatable promoter operably linked to nucleic acid encoding the polypeptide. This is especially true given Applicants' detailed description of cells (see, e.g., the section extending from page 16, line 26 to page 18, line 14) and regulatory promoter systems (see, e.g., the section extending from page 10, line 9 to page 16, line 24). In addition, a person having ordinary skill in the art would have been able to use well known procedures to introduce the obtained cells into the mammal. As taught on page 20, line 10, infusion or injection techniques can be used to introduce cells into a mammal's bloodstream.

A person having ordinary skill in the art also would have been able to following Applicants' teachings to increase or decrease the concentration of an inducing agent to which the cells are exposed thereby causing an increase in expression of the polypeptide at a point after the introducing step. This is especially true given Applicants' detailed description of (1) regulatory promoter systems as noted above, (2) inducing agent dosages set forth on page 6, lines 20-32, and (3) methods for administering inducing agents set forth on page 20, lines 12-17. In particular, page 20, lines 12-17 disclose that the inducing agents (e.g., tetracycline) can be administered orally (e.g., dissolving the inducing agent in drinking water).

Taken together, a person having ordinary skill in the art would have been able to carry out the presently claimed invention without undue experimentation. Thus, Applicants' specification fully enables claims 41-48.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 21-40 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner questioned the clarity of phrases in claims 21, 26, and 27.

Applicants respectfully disagree. Claims 21-40 are clear and unambiguous. To further prosecution, however, claims 21-28 have been rewritten for convenience as claims 41-48 incorporating claim language suggestions provided by the Examiner. In addition, claims 29-40 have been cancelled without prejudice. Thus, this rejection is moot.

A person having ordinary skill in the art at the time Applicant filed would have understood the meaning of present claims 41-48. Thus, claims 41-48 are free of any rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102

The Examiner rejected claims 29-40 under 35 U.S.C. § 102(a) as being anticipated by Cooke (*J. General Virol.*, 78:381-392 (1997)). The Examiner also rejected claims 29-40 under 35 U.S.C. § 102(b) as being anticipated by Knaus (*Mol. Cell. Biol.*, 16:3480-3489 (1996)).

Applicants respectfully disagree. Claims 29-40 are not anticipated by the Cooke or the Knaus reference. Claims 29-40, however, have been cancelled herein. Thus, these rejections are moot.

CONCLUSION

Applicants submit that claims 41-48 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned agent at the telephone number below if such will advance prosecution of this application. Please change the Attorney Docket No. to 07039-416001.